REMARKS

Claims 73-103 were pending in this application. Claims 73, 75, 85, 88, 90, 93, and 102 have been amended. Claim 74 has been cancelled. Upon entry of this Amendment and Response, claims 73 and 75-103 will be pending.

Claim 74 has been cancelled in view of the amendment to claim 73. Support for the amendment to claim 73 can be found in the claims as originally filed and in the the specification at page 17, lines 7-9. Claims 75, 85, 88, 90, 93, and 102 have been amended to correct their respective dependencies in view of cancelled claim 74. The specification has also been amended to correct typographical errors. Support for the amendment to the specification can be found throughout the specification, including at least at page 21, line 8 to page 22, line 33. *No new matter has been added.*

Amendments and cancellations of the claims should in no way be construed as an acquiescence to any of the Examiner's objections and/or rejections. Applicant reserves the option to further prosecute the same or similar claims in the present or another patent application. The amendments and cancellation made to the claims are not related to any issues of patentability.

RESPONSE TO RESTRICTION REQUIREMENT

The Examiner has required restriction between the following inventions in the above-identified application:

Group I: Claims 73, 89-81 and 89, drawn to a method of treating infertility in a female mammal comprising administering a pharmaceutical agent comprising a gonadotrophin releasing hormone (GnRH) agonist which supports the luteal phase;

Group II: Claims 73-76, 85-88, 96 and 97, drawn to a method of treating infertility in a female mammal comprising administering a pharmaceutical agent comprising a GnRH agonist, wherein the additional agent triggering final follicular maturation and ovulation is GnRH agonist administered to support the luteal phase;

Group III: Claims 73-75, 77, 85-88, 90-92, 94 and 95, drawn to a method of treating infertility in a female mammal comprising administering a pharmaceutical agent comprising a

GnRH agonist, wherein stimulation of follicular growth and induction of final follicular maturation and ovulation is effected by the administration of at least one additional agent;

Group IV: Claims 73, 74, 85-88, and 93, drawn to a method of treating infertility in a female mammal comprising administering a pharmaceutical agent comprising a GnRH agonist, wherein the stimulation effected by the administration of the additional agent followed, before ovulation, by an oocyte retrieval procedure, wherein at least one oocyte is obtained;

Group V: Claims 73 and 82, drawn to a method of treating infertility in a female mammal comprising administering a pharmaceutical agent comprising a GnRH agonist, wherein the pharmaceutical agent which supports the luteal phase is administered in combination with an other luteal support agent;

Group VI: Claims 73, 83 and 84, drawn to a method of treating infertility in a female mammal comprising administering a pharmaceutical agent comprising a GnRH agonist, wherein the pharmaceutical agent which supports the luteal phase is administered in combination with a cytokine involved in embryo implantation mechanism;

Group VII: Claims 98-101, drawn to a method of treating infertility in a female mammal comprising administering a pharmaceutical agent which comprises a GnRH agonist comprising buserelin; and

Group VIII: Claims 102 and 103, drawn to a kit for the treatment of infertility in a female mammal comprising a pharmaceutical agent comprising a GnRH agonist and packaging.

The Examiner alleges that the claims lack a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the claims lack the same special technical feature. The Examiner alleges "what is common is known, and if known is not special." The Examiner suggests that Schmidt-Sarosi *et al.* (1995) *J Assisted Repro Gen* 12:167 (cited in ISR) describes a method of treating infertility by administering a GnRH agonist to a female subject in need thereof. The Examiner further states "[t]hus, the reference discloses what is common and known." Based on the teachings of Schmidt-Sarosi *et al.*, the Examiner concludes that the pending claims do not share common technical feature, and, as such, lack unity.

In response, Applicant hereby *traverses* this restriction in view of the amended claims. Claim 73 has been amended to specify a method of treating infertility in a female mammal comprising administering a pharmaceutical agent comprising a gonadotrophin releasing hormone (GnRH) agonist which supports the luteal phase, wherein the GnRH agonist is administered *to the female mammal within the first three days* either after a spontaneous ovulation in the female mammal, or after stimulation of follicular growth and triggering of final follicular maturation and ovulation in the female mammal with at least one additional agent, such that infertility is treated in the female mammal. Independent claim 98 also requires that the GnRH agonist, *e.g.,* buserelin, be administered *within the first three days* following ovulation. Claim 102 has been amended to specify a kit for the treatment of infertility in a female mammal comprising a pharmaceutical agent comprising a GnRH agonist which supports luteal phase, formulated in a dosage and unit required for one cycle of treatment; and packaging which indicates that the GnRH agonist is administered to the female mammal *within the first three days* either after a spontaneous ovulation or after stimulation of follicular growth and triggering of final follicular maturation and ovulation.

Applicant's invention is based, in part, on the discovery of the advantage of administering a GnRH agonist within the first three days following ovulation in a female mammal to treat infertility. Thus, each of the claims requires the special technical feature of the timing of administration, *i.e.,* within three days following ovulation, of administration of the GnRH agonist. This special technical feature is not described in the art cited by the Examiner, as Schmidt-Sarosi *et al.* does not teach administration of a GnRH agonist to a female mammal within the first three days following ovulation for treatment of infertility. In view of the amendment to claims 73 and 102, Applicant submits that claims 73-103 correspond to the same technical features and are connected in design, operation, and/or effect because claims 73-103 do not differ in method steps, parameters, and/or reagents used. Therefore, claims 73-103 are related to the same inventive concept. Applicant respectfully requests that the Examiner reconsider the restriction of Groups I to VIII in view of the amendment to claims 73 and 102. In order to be responsive, however, Applicant hereby elects Group I. Claims that read on elected Group I include claims 73-101.

Should the Examiner disagree with Applicant's position that the amended claims share a common technical feature and, therefore, have a common inventive concept, Applicant

respectfully requests that the Examiner consider regrouping the claims of Groups I and III in view of the amendment of claim 73.

With respect to Groups I, II, III, IV, V, and VI, Applicant respectfully notes that each of these groups include the *generic linking claim of claim 73*. As such, each of the claims in Groups I, II, III, IV, V, and VI share the same common technical feature and are related to the same inventive concept.

With respect to Group VII, the claims of Group VII provide narrower embodiments of the method of claim 73 (Groups I-VI). As such, Applicant respectfully requests that the Examiner reconsider the restriction of Group VII from Groups I, II, III, IV, V, and VI .

Moreover, Applicant respectfully submits that the agents described in Groups II and III are related in that they perform a similar function, and, therefore, request reconsideration of the restriction of the subject matter of these Groups. Group II is directed to a method including the use of an additional agent for stimulating follicular growth and triggering final follicular maturation and ovulation where the additional agent is a GnRH administered to support luteal phase. Group III is drawn to a method including use of an additional agent for stimulating follicular growth and triggering final follicular maturation and ovulation. *An example of an additional agent of Group III is a GnRH agonist described in Group II.* As such, Applicants respectfully request that the Examiner reconsider and regroup Groups II and III.

In sum, should the Examiner disagree with Applicant's traversal of the instant restriction, Applicant respectfully requests that the Examiner reconsider restricting the claims to the original restriction described in the office action of August 29, 2007 which included the following two groups:

Group I: Claims 73-101 drawn to a method of treating infertility in a female mammal comprising administering a pharmaceutical agent comprising a gonadotrophin releasing hormone (GnRH) agonist; or

Group II: Claim 102 (and claim 103) drawn to a kit for the treatment of infertility in female mammals comprising a pharmaceutical agent comprising a (GnRH) agonist and at least one additional agents.

SPECIES ELECTION

The Examiner has also required that Applicant elect the following species:

The Examiner has indicated that Applicant must elect a species of GnRH agonist listed in claim 78 (Species I). Applicant hereby elects "a synthetic peptide agonist of GnRH." The Examiner has indicated that if "a synthetic peptide agonist of GnRH" is elected, Applicant must further elect a synthetic peptide listed in claim 79. Applicant hereby elects "buserelin." Claims that read on the elected species include claims 73, 75-101.

The Examiner has indicated that Applicant must elect a species of pharmaceutical agents listed in claim 82. With respect to claim 82, Applicant hereby elects "natural progesterone." Claims that read on the elected species include claims 73, 75-77, 81, 82, 85-89, and 95.

The Examiner has further required Applicant to elect a species of cytokine listed in claims 83 and 84 (Species III). Applicant hereby elects "native Leukemia Inhibitory Factor (LIF)". Claims that read on the elected species include claims 73, 75-77, 81, 83-89, and 95.

The Examiner also requests Applicant elect an additional agent described in claim 90 (Species IV). With respect to claim 90, Applicant hereby elects "recombinant FSH". Claims that read on the elected species include claims 73, 75-77, 81, 85-90, 95, and 98.

In addition, the Examiner requires Applicant to elect an additional agent as described in claim 93. With respect to claim 93, Applicant hereby elects "hCG." Claims that read on the elected species include claims 73, 75-77, 81, 85-89, 93, 95, and 98.

With respect to the elected species, it is Applicant's understanding that the election of a species and specific species is for searching purposes only. It is also Applicant's understanding that upon allowance of the elected claims, the generic claims also will be searched and Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. *Applicant hereby reserves the right to traverse the species and specific species elections if Applicant's understanding is incorrect.*

SUMMARY

It is respectfully submitted that this application is in condition for allowance. If there are any remaining issues, or if the Examiner believes that a telephone conversation with Applicant's attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at (617) 227-7400. Please charge any additional fees or credit any overpayments to our Deposit Account No. 12-0080, under Order No. KZY-001US from which the undersigned is authorized to draw.

Dated: October 15, 2008

Respectfully submitted,

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